transducer is excited, it produces at least one annular focal zone. Applicant wishes to point out that the term "Vortex transducer" is a naming convention established in the literature, it does not mean the transducer of the present invention creates vortices or vortexes. Applicant cites reference CQ from Applicant's Information Disclosure Statement, filed on 11 June 2004. "Because this form of phasing produces the equivalent of a rotating excitation wave on the face of the transducer with the resultant cyclone-shaped focal region, it is referred to henceforth as a "sector-vortex" applicator." Cain et al., Concentric-Ring and Sector-Vortex Phased-Array Applicators for Ultrasound Hyperthermia. *IEEE Transactions on Microwave Theory and Techniques*, Vol. MTT-34, No. 5, May 1986, p543 (first paragraph). Borrowing from this description in the literature, Applicant describes a mechanical transducer having similar focus characteristics as the "sector-vortex" design described by Cain. Cain et al., described a "sector-vortex" using a phased-array applicator. The present invention eliminates the electronic complexity of a phased-array by using a mechanically formed transducer. Furthermore, Applicant has devised a method of producing a mechanically formed vortex transducer without the need for a separate lens by incorporating a lens *like* function into the mechanically formed vortex ultrasound transducer during the manufacturing process.

The Examiner argues that "The shape of the Levin transducer is irregular so that the resulting ultrasound causes vortex." The Examiner further states in support of a 35 USC §103(a) rejection that "However, Levin et al., remains silent as to detailed structure of the ultrasound transducer." Applicant objects to the inconsistent interpretation of the reference. A detailed analysis of Levin, et al., shows in fact that the former statement is inaccurate, while the later statement is correct.

Levin teaches an ultrasound transmission device. Not an ultrasound transducer. Levin states "The distal end vibrates at ultrasonic frequencies at the treatment site when the energy source is applied to the proximal end." (Col. 2, lines 5-7) Reviewing the specification in detail, it is clear Levin teaches a catheter like device for the transmission of ultrasound energy.

The Levin device is a catheter capable of carrying ultrasound energy from an ultrasound source, down a propagating "horn" and into a narrow body lumen such as a blood vessel. No where in the '703 patent is there a description or teaching of what the ultrasound source looks like, how the transducer itself operates, what kind of focal zone the ultrasound transducer produces or any other feature of the transducer itself. Since the teaching of Levin is in no way relevant to the construction, operation or use of a mechanically formed vortex ultrasound transducer, Applicant respectfully submits that the Levin '703 patent is not relevant and does not anticipate the present invention under 35 USC §102(b).

Applicant now addresses the specific passages cited by Examiner as relevant to the present application. Examiner cites Col. 25, lines 1-12; Col. 7, lines 1-17; and figure 49A as relevant. Levin teaches in Col. 7, lines 1-17, that the ultrasound energy being transmitted through the catheter causes the transmission wire to oscillate to form a standing wave pattern. (col. 7, line 2 & 11) Beyond this reference the '703 specification has references to the standing wave pattern too numerous to detail. The generation of a standing wave is contrary to the production of an annular focal region. To produce a standing wave, two boundaries are required. There must be a transmission point and a reflection point. Thus Levin uses the wire component as the propagation medium for ultrasound energy. The distal tip acts primarily as a reflector. Ultrasound energy is generated on the proximal end of the catheter, and broadcast down the length of the horn. The energy passes into the wire(s) and is reflected off the distal tip and propagates back along the wire(s) to produce a standing wave. Thus the reference of Col. 7, lines 1-17 (as well as the specification in general) is incapable of producing the annular focal region of claim 1. The present invention transmits ultrasound energy directly without a mechanical transmission device. Since the mechanically formed vortex ultrasound transducer of claim 1 has no second surface or point to produce reflection, it is not possible to establish a standing wave as Levin teaches. Clearly then, the '703 patent cannot produce an annular focal region under any circumstance and the cited paragraph does not anticipate the present invention.

Examiner further cites Col. 25, lines 1-12 as anticipating the present invention. Applicant respectfully disagrees. As previously described, no vortex, vortices or vortexes are

formed by the ultrasound transmission of the mechanically formed vortex ultrasound transducer. However even if it were, the vortex referred to by Levin in Col. 25, line 9 is not caused by ultrasound energy. Careful examination of the cited passage reveals the '703 patent teaches a method of advancing the catheter step wise through a thrombus (lines 6-7) and then withdrawing the catheter tip (lines 10-11). The action of advancing and withdrawing the catheter tip creates a vacuum, thus causing a vortex in the bodily fluid. Levin states "This action effectively pulls apart or mechanically disorganizes the blockage by utilizing a vortex to suck the blockage toward the tip ***as the tip is being withdrawn***." (Col. 25, lines 8-11, emphasis added).

With regard to cited Figure 49A, applicant wishes to respectfully point out that the figure is not a transducer, but an alternative embodiment of the distal tip of the catheter. Since the distal tip is not an ultrasound transducer, it cannot be "excited" in the manner of an ultrasound transducer. It can only propagate energy passed into it.

Because the '703 patent does not teach an ultrasound transducer, but an ultrasound transmission device, and for the reasons cited above, Applicant respectfully request the rejection based on 35 USC §102(b) be withdrawn.

35 USC §103(a) Levin et al. in view of Dias

Claims 2-6 stand rejected under 35 USC §103(a) as being unpatentable over Levin et al., as applied to claim 1, and further in view of Dias, et al., in US patent 5,400,788. Applicant respectfully disagrees.

Examiner states that Levin substantially discloses all claimed features of claims 2-6. However, as discussed above, Levin is completely silent as to the size, shape, construction and type of transducer used with the ultrasound transmission device. As such, it is impossible for Levin to disclose the features of the transducer of the present invention, to which pending claims 2-6 relate to.

Since Levin does not detail an ultrasound transducer, it would be impossible to apply the transducer manufacturing technique of Dias et al., to the catheter construction teaching of Levin et al. Furthermore, the teaching of Dias relates to an acoustic wave guide with a

transducer that preferentially generates surface acoustic waves (vs. standard longitudinal transmission waves as used in the present invention). The Dias device acts as a focus prism or collimator of the SAW energy, and converts that energy into longitudinal energy. The focusing of the Dias ultrasound transducers occur on a point at the entry to the acoustic wave guide. Focusing is done by having a spherical shape to the transducer, or mounted on a prism to direct ultrasound energy to the acoustic wave guide.

The operation of the present invention is entirely different. Applicant teaches a method of producing the present invention and utilizes the materials and methods to provide a built in lens. "The resulting molded piezocomposite now has a shape that takes on the shape of a lens. In this manner, a piezoelectrically active lens can be made that is quite rugged, eliminating the need for separate focusing lenses." (Paragraph [0043], lines 31-33). Thus the transducer of the Dias disclosure is not relevant to that of the present invention.

Examiner states that the formation of a standard ultrasound transducer, such as taught in Dias in Col. 6, lines 13-65 would make it obvious to apply Dias to Levine. Applicant reiterates the lack of relevance of Levin as previously discussed. Furthermore Applicant wishes to call attention to the concept of a "...typical ultrasound transducer..." (Detailed Action, Page 3, line 3). Dias transducer is formed from a spherical disc (Col. 6, line 27) with Spherical annulus (*Id.*). The matching layer is made on the inner surface of a sphere (line 30) formed in a smooth spherical surface (line 32). The necessity in Dias for a regular sphere is to allow the transducer elements to have a single focal point 70 at the tip of the acoustic wave guide 72. (Fig. 4, described at Col. 5, line 32 through Col. 7, line 12). Thus by its very nature of being a "typical" ultrasound transducer, it focuses on a single point in space, instead of forming at least one substantially annular focal region as described in the present application. Therefore there is no similarity in the construction of the transducer in the present invention with the teaching of Dias.

In light of the typical formation of the transducer in Dias, and the lack of a transducer description in Levin, Applicant believes there is no reason to combine the references. Furthermore, even if the references are combined, it does not follow that one of ordinary skill in the art would produce a mechanically formed vortex ultrasound transducer. Since both Levin and

Dias deal with ultrasound transmission, it is more likely the combination would yield a catheter, having a prism like acoustic wave guide (in addition to a horn as in Levin) for the transmission of SAW energy into a body lumen, to produce standing waves. This result has no similarity to the present invention and Applicant firmly believes a person of ordinary skill in the art could not possibly find it obvious to produce a mechanically formed vortex ultrasound transducer. Since claims 2-6 depend on novel claim 1, Applicant believes the 35 USC §103(a) rejection cannot stand. Applicant respectfully requests the rejection with regard to 35 USC 103(a) be withdrawn.

Claims 7-9, 11 and 12 of the present application stand rejected as being unpatentable over Levin as in view of Dias. Applicant reiterates the arguments presented above with regard to relevance and obviousness. Furthermore Applicant reiterates the argument that the Levin and Dias combination cannot and will not produce a mechanically formed vortex ultrasound transducer. Applicant is unclear as to why Examiner has cited Figures 1-3 and 4 of the Levin/Dias patents. Levin in Figs. 1-4 illustrates catheters, not ultrasound transducers. Similarly Figs 1-3 of Dias illustrate prior art catheters, not ultrasound transducers. Fig. 4 of Dias provides a cross view of a spherical transducer of Dias having a single focal point 70. Fig. 8 of Dias illustrates a partitioned or diced regularly shaped arrangement of transducer elements. However the specification of Dias is silent with regard to item 102 which indicates the gap space between the transducer elements 98 and 100. Since the specification of Dias does not call out part 102, and there is no suggestion in the text regarding figure 8 of what this gap is, there is no way to infer what item 102 might be. There is also no suggestion that Dias provides for a transducer having the advantage of an integrated lens like feature. Any inference as to what item 102 is would go beyond the written scope of the reference and read material into the prior art based on the present teaching. It is well understood that the applicant's teaching cannot be used to add light to the prior art. For all the reasons reiterated here, and because the Dias patent fails to describe an irregularly shaped transducer construction, Applicant respectfully requests the rejection based on 35 USC §103(b) be withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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